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Subject: Environmental Defense comments on Formaldehyde, Reaction Product with Tetrapropenyl Phenol, Methylamine and Sulfur (CAS# 68855-34-5)

(Submitted via Internet 10/10/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and sarah\_loftus@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the Robust Summary/Test Plan for Formaldehyde, Reaction Product with Tetrapropenyl Phenol, Methylamine and Sulfur (CAS# 68855-34-5).

The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) has submitted a Robust Summary/Test Plan to describe available data and testing needs for Formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur (CAS# 68855-34-5). The resulting reaction products are a mixture of similar, relatively large, lipophilic chemicals varying in the number of sulfur atoms, and alkyl phenols with molecular weights ranging from 967 to 1179. We agree that these reaction products are sufficiently similar or exhibit sufficiently consistent properties that they are appropriately considered one chemical for review under the US HPV program.

The Test Plan submitted for formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur provides a good description of the synthesis, uses, transport and possible sources of environmental release and human and environmental exposure for this chemical. According to the sponsor, it is synthesized in a solvent composed of highly refined lubricant base oil. The active ingredient is never isolated through the course of its use. Its use is apparently restricted to that of a high temperature detergent in lubricating oils used in railroad engines, and the sponsor indicates that the general public does not use it. Potential exposure is hence limited to occupational settings associated with production, transport and service and mechanical work on railroad engines. Of these, mechanics are most likely to be directly exposed to lubricating oils containing formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur. The most likely exposure will be dermal exposure to the finished product that contain concentrations of the HPV chemical ranging from 1 to 3%. Potential release into the environment is somewhat restricted by the fact that use of this product is limited to railroad engines, but some release into the environment is likely in the course of transport, loss from engines and disposal of used oil.

To date, Formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur has been the subject of very little toxicological characterization. Our review of the Test Plan indicates that only two of the requested SIDS elements, vapor pressure and acute toxicity, have been previously addressed. Review of the Robust Summary indicates that the

acute toxicity studies are limited to a dermal study using rabbits and an oral study using rats. Both studies were conducted in 1971, pre-GLP, did not characterize the tested product and used a very limited number of animals. Neither study would meet current standards. These studies do suggest, however, that formaldehyde, reaction product with tetrapropenyl phenol, methylamine and sulfur has low acute toxicity, and we do not recommend their repetition. We do agree with the need to conduct all of the additional studies proposed to address the remaining SIDS elements.

In sum, the Test Plan proposes that each of the SIDS elements not currently addressed by adequate studies be addressed in new studies conducted under appropriate OECD guidelines. We strongly support the proposed studies for this widely dispersed chemical, the results of which should finally provide at least a basic toxicological characterization.

Thank you for this opportunity to comment.

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